IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY *Plaintiff*,	)	
v.	)	Civil Action No. 4:21-cv-01058-P
UNITED STATES FOOD AND DRUG ADMINISTRATION, *Defendant*.	)	

APPENDIX IN SUPPORT OF DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

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Dated: October 17, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 17, 2024, I electronically filed this document with the Clerk of the Court for the United States District Court for the Northern District of Texas by using the CM/ECF system. Counsel in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

/s/ Andrew F. Freidah
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United States Department of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:21-cv-01058-P

DECLARATION OF SUZANN BURK

I, Suzann Burk, hereby declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA" or "the agency"), in Silver Spring, Maryland.

2. A summary of my work experience and current job responsibilities is included in paragraph 2 of my declaration in this matter dated December 6, 2021. Burk December 2021 Decl., ECF No. 23, Ex. A.

3. The statements contained in this declaration are based upon my personal knowledge, and upon information I have learned in my official capacity.

4. As explained in my December 2021 declaration, one of DDOM's three branches is the Access Litigation and Freedom of Information Branch ("ALFOI"), which is primarily responsible for the review and disclosure of CBER-maintained records in response to Freedom of Information Act ("FOIA") requests and FOIA litigation. *See* Burk December 2021 Decl. ¶¶ 3, 5.

5. The purpose of this declaration is to explain the biological product licensing process, to explain the confidentiality of biological product licensing files, to explain ALFOI's receipt and handling of the FOIA Request submitted by Plaintiff Public Health and Medical Professionals for Transparency ("PHMPT"), and to explain ALFOI's search for records responsive to PHMPT's FOIA Request.

THE BIOLOGICAL PRODUCT LICENSING PROCESS

6. Vaccines are biological products that are regulated under the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(i)(1); as well as "drugs" subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(g)(1)(B). Vaccines are approved for marketing through applications known as Biologics License Applications ("BLA"). 42 U.S.C. § 262(a). A vaccine that is the subject of an approved BLA need not also obtain approval via a new drug application under 21 U.S.C. § 355. 42 U.S.C. § 262(a), (j).

7. A sponsor of a biological product usually begins the process of studying an investigational product by performing a variety of laboratory tests on it, including certain safety tests in animals. The sponsor's focus at this stage is to collect the data and information necessary to establish that the investigational product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. Before the investigational biological product may be administered to human subjects, however, the sponsor must first submit an investigational new drug application ("IND") to FDA. *See* 21 C.F.R. § 312.20; *see generally* 42 U.S.C. § 262(a)(3),

21 U.S.C. § 355(i), and 21 C.F.R. Part 312.

8. In general, an IND application contains the results of the laboratory and animal tests (referred to as pre-clinical data) that have been performed, gathered, and submitted by the sponsor; manufacturing information for the investigational biological product; and proposals, known as protocols, describing the sponsor's plans for testing the investigational biological product in human subjects. *See generally* 21 C.F.R. § 312.23. Tests conducted in human beings are referred to as clinical trials. FDA medical and scientific reviewers evaluate the data submitted in the IND, including the proposed clinical trial protocols. If the reviewers determine, from the evidence, that the biological product does not pose an unreasonable or significant risk of illness or injury to human subjects and if there are no other problems with the submission that cause the agency to identify the need for a clinical hold, the agency will not bar the clinical trial from proceeding. Given that an IND is submitted during the investigational stage of drug development, IND files may contain data and information regarding formulations, dosages, or uses that differ from those that are ultimately licensed.

9. A subsequent stage of the development process may occur when a sponsor submits to FDA a formal application for licensing (*i.e.*, marketing approval), the BLA. *See* 42 U.S.C. § 262(a)(1)(A). BLAs include various information and data, including nonclinical and clinical data; information about manufacturing methods and locations; data establishing stability of the product through the dating period; summaries of results from tests performed on the lots of representative samples of the product; and, among other things, mockups of the labels, enclosures, medication guide if proposed, and containers as applicable. *See* 21 C.F.R. § 601.2(a); *see also, e.g.*, eCTD v4.0 Comprehensive Table of Contents Headings and Hierarchy (version 2.1) (Sept. 2024) ("BLA Table"), https://www.fda.gov/media/179699/download?attachment (laying out

organization for BLAs).

10. Under the PHSA, FDA approves a BLA on the basis of a demonstration that: (1) the vaccine is "safe, pure, and potent;"[1] and (2) the facility in which the vaccine is produced meets standards designed to assure that the vaccine continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C)(i). The applicant must also consent to inspection of the manufacturing facility. *Id.* § 262(a)(2)(C)(ii). If FDA determines that the application meets statutory and regulatory requirements, it will issue a biologics license for the product, thus authorizing the sponsor of that particular BLA to market that new product. *See* 21 C.F.R. § 601.4(a).

11. IND and BLA files continue to be maintained following initial licensure of a product, and sponsors may continue to make submissions to the relevant file. For example, clinical trial data for formulations, dosages, or uses that differ from the licensed vaccine could be submitted to the IND file; and certain post-licensure submissions for the licensed vaccine (such as narrative periodic reports) would be submitted to the BLA file.

CONFIDENTIALITY OF BIOLOGICAL PRODUCT LICENSING FILES

12. FDA regulations at 21 C.F.R. § 601.50 and 601.51 (along with the FOIA, other relevant statutes, and FDA's other regulations regarding disclosure of records) govern the availability of data and information in IND and BLA files. *See also* 21 C.F.R. § 312.130(b).

13. Under 21 C.F.R. § 601.50, the existence of an IND will not be disclosed by FDA unless it has previously been publicly disclosed or acknowledged, and the availability for public disclosure of data and information in an IND file for a biological product is handled in accordance

[1] The standard for licensure of a biological product as potent under 42 U.S.C. § 262 has long been interpreted by FDA to include effectiveness. *See* 21 C.F.R. § 600.3(s); Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (May 1998), at 4, https://www.fda.gov/media/71655/download.

with 21 C.F.R. § 601.51.

14. Section 601.51 is titled "Confidentiality of data and information in applications for biologics licenses" and defines, for the purposes of that regulation, the term "biological product file" ("BPF") to include, among other things, the BLA and INDs incorporated into the BLA. *See* 21 C.F.R. § 601.51(a). Section 601.51 states that, unless a BPF has been previously disclosed or acknowledged, FDA cannot disclose its existence or any data or information therein before a BLA has been approved. *See* 21 C.F.R. § 601.51(b)-(c).[2]

15. Once a biologics license has been issued, certain data in the BPF is available for public disclosure upon receipt of a FOIA request. *See, e.g.*, 21 C.F.R. § 601.51(e); 21 C.F.R. § 20.20; 21 C.F.R. § 20.23.

16. Section 601.51(e) lists the type of information in a BPF that is available for public disclosure following licensure.[3] 21 C.F.R. § 601.51(e) is not a list of items that must be in a BPF; rather, it describes information that, if found in a BPF, may generally be disclosed absent

[2] If the existence of a BPF has been publicly disclosed or acknowledged, FDA generally still cannot make information and data in the file available for public disclosure until a license has been issued. *See* 21 C.F.R. § 601.51(d).

[3] 21 C.F.R. § 601.51(e) states: "After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 20.61 of this chapter. (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 20.81 of this chapter. (5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in § 20.61 of this chapter. (6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of part 20 of this chapter. (7) All records showing the manufacturer's testing of a particular lot, . . . manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 20.61 of this chapter. [and] (8) All records showing the testing of and action on a particular lot by the Food and Drug Administration."

extraordinary circumstances. In kind, 21 C.F.R. § 601.51(f) lists the type of information that, if found in a BPF, generally cannot be publicly disclosed even after a biological product is licensed.

ALFOI'S HANDLING OF PLAINTIFF'S FOIA REQUEST

17. On August 27, 2021, Plaintiff submitted its FOIA Request to FDA seeking: "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." Pl.'s FOIA Request (ECF No. 1-1), at 1; *see* Declaration of Sarah Kotler ("Kotler Decl.") (ECF No. 30, Ex. D) ¶ 15. Plaintiff's Request further clarified that (a) "Pfizer Vaccine" meant "the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty . . . for individuals 16 years of age and older" and (b) its Request "include[ed] but [was] not limited to all data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)." Pl.'s FOIA Request (ECF No. 1-1) at 1 & n.2.

18. FDA assigned Plaintiff's FOIA Request the control number 2021-5683.

19. On September 9, 2021, FDA denied Plaintiff's request for expedited processing, *see* Ltr. From FDA to PHMPT (ECF No. 1-4); Kotler Decl. ¶¶ 17-21, and the FOIA Request entered ALFOI's complex queue for processing.

20. Before Plaintiff's Request came up in the queue, Plaintiff filed the present action. *See* Compl. for Declaratory & Inj. Relief (ECF No. 1) (Sept. 16, 2021).

21. In the ensuing few months, given the breadth of Plaintiff's FOIA Request, the limited resources of ALFOI, and the large amount of information that had already been made publicly available about Comirnaty, FDA attempted to engage with Plaintiff for Plaintiff to more narrowly identify the records of greatest interest and agree to a reasonable processing schedule.

22. Between November 17, 2021, and January 31, 2022, ALFOI produced 13,727

pages of responsive records to Plaintiff that Plaintiff had identified as "priority" records.

23. On January 6, 2022, this Court ordered a processing schedule of 55,000 pages every thirty days. On February 2, 2022, upon consideration of the agency's motion to partially modify the January Order to "stand up" unprecedented and extraordinary operations to comply with the Order, the Court allowed for a graduated processing schedule, which required CBER to process 10,000 pages per month in March and April 2022; 80,000 pages per month in May, June, and July 2022; 70,000 pages in August 2022; and 55,000 pages per month thereafter. ECF No. 56 ("February 2, 2022 Order"). To the extent CBER processed more than the required page count in any month, the Court permitted CBER to "bank" the extra pages and apply them to a later month toward its quota for that month. *Id.*

24. Pursuant to the Court's February 2, 2022 Order, ALFOI processed 1,187,147 pages of responsive records over the course of twenty-one months and spent more than $3.5 million through October 2023 to do so.[4]

25. Combined with the 13,727 pages of records produced prior to the Court's February 2, 2022 Order, FDA processed a grand total of 1,200,874 pages of responsive records in response to Plaintiff's FOIA Request.

ALFOI'S SEARCH FOR THE COMIRNATY BIOLOGICAL PRODUCT FILE

26. Initially, ALFOI interpreted Plaintiff's FOIA Request as a "request for all publicly releasable information in the original biologics license application submitted by BioNTech-Pfizer

[4] Following the Court's February 2022 Order, and the Court's June 12, 2023 production order in *PHMPT v. FDA*, 22-cv-915 (N.D. Tex.) ("*PHMPT 2*") (requiring FDA to process across the two cases at least 90,000 to 110,000 pages per month from July 2023 through November 2023 and, starting in December 2023, in *PHMPT 2*, at least 180,000 pages per month until June 2025), FDA has sought stays in other FOIA litigations citing the voluminous production requirements in both PHMPT cases. To date, 7 stays have been granted, and 3 stay requests are awaiting decisions.

for the Comirnaty vaccine" with internal file number STN 125742/0/0 and STN 125742/0/1. *See* Burk Dec. 2021 Decl. ¶ 25.[5] In other words, ALFOI initially interpreted Plaintiff's FOIA Request as seeking publicly releasable portions of Pfizer's initial BLA submissions (through May 18, 2021). However, in the spirit of the Court's comments during its 2021 and 2022 hearings with the parties and in an attempt to provide Plaintiff with the greatest scope of data and information that the literal language of its FOIA Request could support, ALFOI searched for and processed the entirety of the BPF for the Pfizer-BioNTech Comirnaty vaccine approved for individuals 16 years of age and older ("original Comirnaty vaccine licensure") through October 27, 2021, the date ALFOI began its search.

27. The BPF, defined by 21 C.F.R. § 601.51(a), is composed of, not only the BLA, but also "all data and information submitted with or incorporated by reference in [the BLA], INDs incorporated into any such application, master files, and other related submissions." Discussed in detail below, ALFOI conducted an expansive search across multiple, independent filing systems for the following records related to the original Comirnaty vaccine licensure through the search cut-off date of October 27, 2021: (i) records submitted by Pfizer to the BLA prior to licensure; (ii) records submitted by Pfizer to the BLA following licensure; (iii) FDA-generated records routinely prepared and filed during review of BLA submissions; (iv) IND records incorporated into the BLA; (v) master file records referenced in the BLA; (vi) other records incorporated by

[5] For BLAs, an applicant may submit rolling submissions so long as they have identified the submission accordingly (*e.g.*, part 1 of 2). STN 125742/0/0 was part of a rolling submission by Pfizer, which included two separate submissions: part 1 of 2 (STN 125742/0/0, submitted on May 6, 2021) and part 2 of 2 (STN 125742/0/1, submitted on May 18 2021). My December 2021 declaration mistakenly omitted a reference to STN 125742/0/1, which ALFOI also considered responsive to Plaintiff's FOIA Request at the time. *See* Burk December 2021 Decl. ¶ 25.

reference into the BLA; and (vii) other related submissions for the original licensure (Biological Product Deviation Reports, certain lot release materials, and lot distribution reports).

Biologics License Application Submissions

28. The bulk of the BPF is the BLA. BLAs are organized by when the information is submitted by a sponsor and then by subject matter category: namely, Module 1 Administrative Information (*e.g.*, cover letters, general correspondence, and FDA Forms); Module 2 Summaries (*e.g.*, pharmacokinetics and quality); Module 3 Quality Information (*e.g.*, chemistry, manufacturing, and controls); Module 4 Nonclinical Study Reports; and Module 5 Clinical Study Reports. Each module contains specific folders and subfolders, to which sponsors electronically submit records. *See, e.g.*, BLA Table. This organization facilitates the agency's review because the BLA is not a single submission; the application process takes a significant period of time, and, ordinarily, sponsors submit new and additional data ("amendments") as the clinical investigations continue and as the agency raises questions during its review process that require further investigations and submissions.

29. BLA submissions are tracked by an FDA database called Regulatory Management System-Biologics Licensing Application (RMS-BLA), which assigns each BLA a unique submission tracking number ("STN"). The STN for Pfizer's BLA for the original Comirnaty vaccine licensure is 125742. BLA submissions are downloadable from an FDA database called Lorenz docuBridge. Accordingly, ALFOI reviewed Lorenz docuBridge for STN 125742 and learned that Pfizer had made 77 submissions to STN 125742/0: 2 containing the original BLA application (STN 125742/0/0 and STN 125742/0/1) and 75 subsequent BLA amendment submissions up until the date of licensure. ALFOI also discovered that between licensure and October 27, 2021, Pfizer made additional submissions to STN 125742, and, upon subsequent

review, ALFOI determined that 26 such submissions were responsive (post-marketing commitment/requirements ("PMC/Rs"), product correspondence, labeling and promotional material, and narrative periodic safety reports submitted to the BLA and related to the original Comirnaty vaccine licensure).

30. These BLA submissions consisted of various Module 1-5 records, including but not limited to individual Case Report Forms ("CRFs"),[6] and clinical data files.

31. ALFOI processed the 77 pre-licensure submissions and the 26 post-licensure submissions (approximately 1,079,089 pages)[7] in response to Plaintiff's FOIA Request.

FDA-Generated Records Related to the BLA

32. CBERConnect is a centralized database for reviewers to electronically upload/file, search, and view, among other things, agency-generated records related to the licensing process. Using CBERConnect, ALFOI again searched for STN 125742 and identified 135 records generated by FDA in response to, or in conjunction with, Pfizer's 77 BLA submissions prior to licensure and 11 records generated by FDA in response to, or in conjunction with, Pfizer's 26 BLA submissions post-licensure (through October 27, 2021). The FDA-generated records related to STN 125742 included, among other things, memoranda of teleconferences between FDA and Pfizer, agency review memoranda evaluating the BLA submissions, agency information requests to Pfizer, and inspection records.

[6] For BLAs, applicants generally submit case report forms for deaths, other serious adverse events, and withdrawals from a study due to adverse events, or as additionally requested by FDA. *See* Guideline for Industry: Structure and Content of Clinical Study Reports (ICH E3) (July 1996), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e3-structure-and-content-clinical-study-reports.

[7] Forty lines per page for data files.

33. ALFOI processed the 146 FDA-generated records in response to Plaintiff's FOIA Request.

Investigational New Drug Application Records Incorporated into the BLA

34. IND submissions are tracked by an FDA database called Biologics Investigational and Related Applications Management System (BIRAMS), which assigns each IND a submission tracking number (called an "Investigational and Related Applications (IRA) number"). The IRA number associated with the original Comirnaty vaccine is 19736.

35. It is standard practice for sponsors and FDA reviewers to refer to IND records by IRA number. So, ALFOI searched for "19736" across the 103 BLA submissions and identified 51 records referenced by tracking number or description/date that were incorporated into the original Comirnaty vaccine licensure.

36. ALFOI also searched for "19736" across the 146 FDA-generated records to determine whether there were any additional identifiable portions of IND 19736 incorporated into the BLA. ALFOI identified 279 additional IND records from that review.

37. ALFOI processed the 330 aforementioned IND records in response to Plaintiff's FOIA Request.

Drug Master Files

38. ALFOI also searched for master files referenced by Pfizer in the BLA. A drug master file ("DMF") is a submission to FDA that provides confidential, detailed information about, among other things, the facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs. The submitter is called a DMF holder. DMF holders can be makers of container closures used for a vaccine, for example. The purpose of a DMF is so that the proprietary information therein is allowed to be incorporated by reference by sponsors of products

seeking approval or licensure for FDA's consideration during review of the sponsor's application without the owner of the master file having to disclose the information in the master file. While the sponsors obtain a right of reference to the DMF by the DMF holder's Letter of Authorization ("LOA"), the information in the DMF itself is not disclosed to the sponsor. FDA ordinarily neither independently reviews nor approves DMF submissions. Instead, FDA customarily reviews the technical contents of DMFs only as is relevant to, and in connection with, the review of applications that reference them. *See* Draft Guidance[8] for Industry: Drug Master Files (Oct. 2019), https://www.fda.gov/media/131861/download; 21 C.F.R. § 314.420.

39. Subfolder 1.4.2 of the BLA is "Statement of right of reference." BLA Table, at 1. ALFOI looked to that subfolder of STN 125742 to identify the DMFs to which Pfizer had obtained a right of reference. The submission for that subfolder identified 8 letters of authorization for 8 DMFs. All the DMFs were Type III DMFs, meaning that they were related to packaging material. *See* 21 C.F.R. § 314.420(a)(3); 84 Fed. Reg. at 30,970 (FDA's approach to "the terminology for types of master files used for the PHS Act [(*i.e.*, biological products)] has generally tracked its approach to the types of DMFs (*e.g.*, Type II, Type III) used for products regulated under the [FDCA]"). Type III DMFs include information such as the packaging materials' intended use, components, composition, and controls for release, as well as the names of suppliers or fabricators of the components and their acceptance specifications. The 8 DMFs supporting STN 125742 were for glass vials and stoppers.

[8] Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue. 21 C.F.R. § 10.115(b). Guidances that are available as drafts on FDA's website are available for public comment and later consideration by the agency of those comments before issuing an updated draft or a final guidance. *See* 21 C.F.R. § 10.115(g).

40. The 8 DMFs identified by ALFOI were maintained by FDA's Center for Drug Evaluation and Research ("CDER"). ALFOI contacted CDER's Division of Information Disclosure Policy ("DIDP") to request DIDP's assistance in retrieving the DMFs; all but one DMF was in paper format and archived at an off-site records storage facility.

41. After all 8 DMFs were retrieved, CDER processed them in response to Plaintiff's FOIA Request.

Other Records Incorporated by Reference

42. ALFOI also reviewed the BLA records for references to records in the emergency use authorization ("EUA") file for the COVID-19 vaccine for individuals 16 years of age and older, which had been authorized prior to Pfizer's submission of its BLA. EUA records are tracked in BIRAMS, and the IRA number associated with Pfizer's COVID vaccine EUA file is 27034. It is standard practice for sponsors and FDA reviewers to refer to EUA records by IRA number. So, ALFOI searched for "27034" across the 103 BLA submissions and 146 FDA-generated records. That search resulted in 44 references, and ALFOI determined that they did not incorporate by reference any EUA-file records. Instead, the references were "mis-hits" (*e.g.*, reflecting a portion of a clinical trial participant identification number), were for background or informational purposes only (*i.e.*, they did not incorporate by reference a specific EUA record), or were duplicative of BLA submissions or IND submissions already processed in response to Plaintiff's FOIA Request.

43. During the course of its review of BLA records, ALFOI also identified that Pfizer had made a submission called a summary monthly safety report ("SMSR") to the BLA that Pfizer called SMSR #10. Accordingly, ALFOI searched for and located SMSRs #1-9 and accompanying submission records (which were all in IND 19736), and FDA-generated records reflecting review

of these SMSRs (found through CBERConnect) and processed them in response to Plaintiff's FOIA Request.

Biological Product Deviation Reports

44. ALFOI also searched for Biological Product Deviation Reports ("BPDRs"). BPDRs are reports by manufacturers of changes or unexpected events that occur during manufacturing that have the potential to affect the safety, purity, or potency of the biological product. Such reporting typically includes any event in the manufacturer's facility involving a distributed biological product that represents a deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications; or an unexpected or unforeseeable event.

45. BPDRs are accessible through the CBER Error and Accident Reporting System ("CEARS"), which is utilized by CBER's Program Surveillance Branch in its Division of Inspections and Surveillance in the Office of Compliance and Biologics Quality ("OCBQ"). ALFOI contacted the Program Surveillance Branch asking for "any BPDRs submitted for [the] Pfizer Comirnaty covid vaccine" through October 27, 2021. The Branch did not locate any BPDRs during that time period for the licensed Comirnaty vaccine.

Lot Release Materials and Lot Distribution Reports

46. ALFOI also searched for submissions related to lot release. Lot release is a system that permits FDA to verify product quality through protocol review and sample testing of biological products. FDA regulations provide that "[n]o lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product." 21 C.F.R. § 610.1. FDA works with sponsors during the BLA review process to develop lot release protocols (*i.e.*, specific quality testing, agreed upon by FDA) to be

used on each lot of products before distribution. In accordance with 21 C.F.R. § 610.2(a), CBER may require manufacturers to submit for CBER review and confirmatory testing samples of any lot of a licensed product, together with the protocols showing results of applicable tests when deemed necessary for the safety, purity, or potency of the product. Following CBER review, FDA will notify the sponsor whether the lot is "released." *See* 21 C.F.R. § 610.2(a).

47. Lot release protocols are accessible to agency employees in CBERConnect. ALFOI searched CBERConnect for lot release protocols associated with STN 125742 and located 11 lot release protocols submitted by Pfizer before the licensure date of August 23, 2021 and 2 lot release protocols submitted between licensure and October 27, 2021.

48. ALFOI processed the 13 lot release protocols in response to Plaintiff's FOIA Request.

49. With respect to the lot release letters, ALFOI was aware that 7 responsive lot release letters had been publicly posted to FDA's website as previously released in response to prior FOIA requests.

50. ALFOI also contacted CBER's Product Release Branch in its Division of Manufacturing and Product Quality asking for "any associated Lot Release Letters for the product Comirnaty" through October 27, 2021. The Product Release Branch provided ALFOI 2 letters within the relevant date range (i.e., before October 27, 2021), and ALFOI determined that they, along with the 7 aforementioned letters, were already accessible on FDA's website at https://www.fda.gov/media/162868/download?attachment (file name: Pfizer-BioNTech Comirnaty STN 125742 COVID-19 Vaccine Lot Notifications (2021).pdf). Accordingly, ALFOI did not re-process these records, but ALFOI alerted Plaintiff's counsel to their availability on FDA's website in the production cover letter dated November 1, 2023, and provided courtesy

copies of them in the November 1, 2023 production. A true and correct copy of ALFOI's November 1, 2023 production letter is attached as Exhibit 1.

51. To locate the records reflecting CBER's testing of lots for the original Comirnaty vaccine licensure, ALFOI contacted CBER's Division of Biological Standards and Quality Control asking for "any possible CBER Testing records related to the product Comirnaty (STN 125742)[;] . . . these would be records where CBER conducted the tests on the product." The Division's Quality Assurance Branch responded by providing ALFOI with 5 testing review memos for lots within the relevant date range (*i.e.*, before October 27, 2021). ALFOI determined that 2 of the 5 records were duplicative of records it had identified in its search for FDA-generated records related to the BLA, and it processed the other 3 testing review memos in response to Plaintiff's FOIA Request.

52. Finally, ALFOI determined that it did not need to search for lot distribution reports submitted by Pfizer related to STN 125742, because an FDA-generated record related to the BLA (that ALFOI processed in response to Plaintiff's FOIA Request) reflected that Pfizer had requested, and FDA had approved, a waiver allowing Pfizer's first report to be filed in January 2022 (after the October 27, 2021 search cut-off date). Still, to ensure its interpretation of the FDA-generated record was accurate, ALFOI shared the FDA-generated record with CBER's Division of Pharmacovigilance in its Office of Biostatistics and Pharmacovigilance, who confirmed it "[did] not have a lot distribution reports [*sic*] submitted for STN 125742 prior to 10/27/2021." Lot distribution reports reflect information about the quantity of product distributed under a license in the timeframe covered by the report, and waivers are governed by 21 C.F.R. § 600.81.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on October 16, 2024.

Suzann H. Burk -S

Digitally signed by Suzann H. Burk -S
Date: 2024.10.16 16:12:46 -04'00'

Suzann Burk
Director
Division of Disclosure and Oversight Management,
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Resources

Exhibit 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

November 1, 2023

Mr. Aaron Siri
Siri & Glimstad LLP
745 Fifth Ave.
New York, NY10151

Sent via email: aaron@sirillp.com

Re: FDA FOIA Request 2021-5683; *Public Health and Medical Professionals for Transparency v. FDA*, 21-cv-01058-P

Dear Mr. Siri,

This is in final response to the Freedom of Information Act (FOIA) request number **2021-5683** that is the subject of the Complaint filed in *Public Health and Medical Professionals for Transparency v. FDA*, 21-cv-01058, now pending in the U.S. District Court for the Northern District of Texas.

Enclosed are 1,853 pages of records and a 1-page slipsheet. The 1,853 pages are marked with Bates numbers FDA-CBER-2021-5683-1148982 to 1150834 some of which contain redactions to prevent the disclosure of material exempt from disclosure pursuant to the FOIA.

Additionally, there are Drug Master File (DMF) records (Bates numbers FDA-CBER-2021-5683-1150835 to 1200874) associated with DMF #s 9543, 10953, 11321, 11793, 11820, 12683, 15209, and 31786 totaling 50,040 pages that are being Withheld in Full as exempt from disclosure pursuant to the FOIA. These records are embodied by the enclosed 1-page slipsheet.

In total, this production reflects 51,893 pages of records.

We have withheld pages or portions of pages under Exemption (b)(4), 5 U.S.C. § 552(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

We have withheld portions of pages, that are subject to the deliberative process privilege, under Exemption (b)(5), 5 U.S.C. § 552(b)(5). That exemption permits the withholding of inter-and intra-agency records which are, among other things, pre-decisional and deliberative, and for which it is reasonably foreseeable that disclosure would harm the interest protected by the exemption.

We have withheld portions of pages under FOIA Exemption (b)(6), 5 U.S.C. § 552(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

We have withheld portions of pages under Exemptions (b)(7)(C) and (E), 5 U.S.C. § 552(b)(7)(C), (E). Those exemptions protect from disclosure records or information compiled for law enforcement purposes, to the extent that the production (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy, and (E) would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law.

Pursuant to the Court's February 2, 2022, order, FDA may "bank" any processed pages in excess of its monthly quota. To date, FDA has banked the following number of pages for potential use against future production obligations:

Production Date	Pages Required	Pages Processed	Pages Banked
3/1/2022	10,000	10,554	554
4/1/2022	10,000	11,043	1,043
5/2/2022	80,000	90,702	10,702
6/1/2022	80,000	90,640	10,640
7/1/2022	80,000	90,877	10,877
8/1/2022	70,000	88,656	18,656
9/1/2022	55,000	88,142	33,142
10/3/2022	55,000	55,474	474
11/1/2022	55,000	55,161	161
12/1/2022	55,000	55,139	139
1/3/2023	55,000	58,725	3,725
2/1/2023	55,000	56,874	1,874
3/1/2023	55,000	13,492	-41,508
4/3/2023	55,000	5,506	-49,494
5/1/2023	55,000	55,097	97
6/1/2023	55,000	55,049	49
7/3/2023	55,000	55,180	180
8/1/2023	55,000	57,311	2,311
9/1/2023	55,000	64,821	9,821
10/2/2023	55,000	76,811	21,811
11/1/2023	*Final Production*	51,893	*Final Production*
TOTAL		**1,187,147**	

Finally, prior to the Court's February 2, 2022 order, FDA also produced 13,727 pages of records to you between November 17, 2021 and January 31, 2022. Accordingly, FDA has processed a total of 1,200,874 pages for the above referenced FOIA request (Bates numbers FDA-CBER-2021-5683-0000001 to 1200874). This response concludes FDA's processing and production of records for the above referenced FOIA request.

As a courtesy, we have also included copies of action package records and lot distribution letters that are part of the Biological Product File and are publicly available, with redaction of material exempt from disclosure pursuant to the FOIA, on the FDA website. The action package records are available here: https://www.fda.gov/media/151710/download?attachment, https://www.fda.gov/media/151733/download?attachment and https://www.fda.gov/media/152252/download?attachment. The lot distribution records are available in the PDF entitled "Pfizer-BioNTech Comirnaty STN 125742 COVID-19 Vaccine Lot Notifications (2021).pdf" here: https://www.fda.gov/media/162868/download?attachment.

Please note, these courtesy copies have not been marked with Bates numbering as they are not being included in the production page count.

Please direct any questions regarding this response to Antonia Konkoly of the Department of Justice, at (202) 514-2395 or Antonia.Konkoly@usdoj.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
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Beth Brockner Ryan
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Enclosure(s)

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